

**Submitter :** Mr. Kenneth Raske

**Date:** 10/29/2007

**Organization :** GNYHA

**Category :** Hospital

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment.

CMS-2213-P-53-Attach-1.PDF




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**Greater New York Hospital Association**

555 West 57th Street / New York, N.Y. 10019 / (212) 246-7100 / FAX (212) 262-6350  
 Kenneth E. Raske, President

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October  
 Twenty-nine  
 2007

**VIA ELECTRONIC MAIL**

Kerry Weems  
 Acting Administrator  
 Centers for Medicare & Medicaid Services  
 Department of Health and Human Services  
 Attn: CMS-2213-P  
 Hubert Humphrey Building  
 200 Independence Avenue, SW  
 Room 445-G  
 Washington, DC 20201

**RE: CMS-2213-P; Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit; Proposed Rule (Vol. 72, No. 188), September 28, 2007**

Dear Mr. Weems:

Greater New York Hospital Association (GNYHA), which represents more than 150 private, not-for-profit and public hospitals in the New York metropolitan area, appreciates the opportunity to comment on the Center for Medicare & Medicaid Services (CMS) proposed rule on the definition of hospital outpatient services and the calculation of the Medicaid upper payment limit (UPL).

The proposed rule would significantly narrow the definition of outpatient hospital services and would stipulate the methodology used by states to calculate the UPL for hospital outpatient services and private clinics.

**Regulation Violates the Moratorium**

GNYHA believes that the proposed rule violates the moratorium enacted by *U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007* (P.L. 110-28), which was signed into law on May 25, 2007. Since provisions contained in the proposed rule are clearly based on policies and provisions subject to the moratorium enacted in P.L. 110-28, we believe that CMS should formally withdraw its proposal.

The proposed rule violates the moratorium by prohibiting states from including graduate medical education (GME) costs in the calculation of the outpatient UPL—a prohibition in direct conflict with the moratorium, which specifically precludes CMS from promulgating or implementing any rule or provisions which restrict payments for GME. GNYHA previously submitted comments in opposition to CMS’s proposed regulation to eliminate Federal financing for Medicaid GME (*Medicaid Program; Graduate Medical Education*, vol. 72, no. 99, May 23, 2007) in a letter dated June 22, 2007, and we reiterate our strong opposition to this proposed policy.

In addition, the proposed rule would modify the categories used to classify providers for purposes of the outpatient UPL calculation to effectively match those provider categories that are the subject of the moratorium by similarly removing the reference to facility ownership (CMS-2258, “Cost Limit Rule”). Classifying providers into the appropriate category is important because each distinct provider category has a separate UPL calculation. The current provider categories are as follows: a) state government-owned or -operated facilities, b) non-state government-owned or -operated facilities, and c) privately owned and -operated facilities. CMS’s proposed provider categories in this regulation (state government, non-state government, and private) clearly have the same policy intent as those contained in the rule subject to the moratorium (state government-operated, non-state government-operated, and private), and the proposed rule therefore violates the moratorium enacted by Congress.

#### **Definition of Hospital Services**

The proposed rule would severely restrict the definition of hospital outpatient services for the Medicaid program to those services that are included in the Medicare outpatient prospective payment system (OPPS) or are paid by Medicare as an outpatient hospital service under an alternate payment methodology. CMS’s stated policy rationale for this change is that the Agency is concerned that the current regulatory definition of Medicaid outpatient hospital services is too broad and that there is a “high possibility of overlap between outpatient hospital services and other covered benefits.” CMS believes that the resulting impact of the purported overlap is that payments may be higher under the outpatient hospital benefit than are otherwise provided under the State plan.

CMS provides absolutely no evidence to substantiate its concern that states are including non-hospital services in their outpatient hospital Medicaid service benefits. In fact, in the proposed rule, CMS references that it has approved 32 state plans for hospital outpatient services over the past four years and that only one state currently defines non-hospital services as part of the outpatient hospital Medicaid state plan service benefit. Given this analysis, CMS has not demonstrated a factual justification for proposing such a restrictive policy, particularly when it has the means at its disposal through reviews of State Plan Amendments to detect and address offending situations if and when they occur.

The proposed change in the definition of outpatient hospital services is contrary to the Medicaid program’s longstanding policy and statutory framework of allowing states flexibility in the development of their programs. Moreover, there is no reasonable policy rationale for so closely aligning the two programs as they generally serve two completely different populations: the Medicaid program primarily serves children and their mothers and the Medicare program primarily serves the elderly. The health care service needs of these populations are quite different

and it is highly inappropriate to restrict the hospital outpatient benefits provided under the Medicaid program to those provided under the Medicare program.

Furthermore, by restricting the definition of hospital outpatient services, the proposed rule would reduce the flexibility of states to utilize their own reimbursement methodologies and inappropriately impinge upon their local determinations of what is most appropriate for their health care systems. For example, the New York State Medicaid program uses many all-inclusive rate methodologies for hospital outpatient services that include both facility and professional fees. Under the proposed rule, such reimbursement methodologies would no longer be permitted and significant statutory and regulatory changes, as well as changes to the current State Plan, would be required to decouple the payments.

GNHYHA is also very concerned that changing the definition of allowable hospital outpatient services may have a major impact on hospitals' disproportionate share (DSH) payments. Under the current regulations, only hospital inpatient and outpatient services are recognized in the calculation of DSH payments. By narrowing the definition of an allowable hospital outpatient service, we are concerned that CMS may be tempted to try to similarly restrict the services included in the calculation of the hospitals' DSH cap. This would have significant and serious funding implications for hospitals that receive and rely upon this critical supplemental funding. DSH payments partially offset the losses hospitals incur in treating Medicaid and uninsured patients, and a reduction in this funding would directly impact their ability to continue to provide access to hospital services for Medicaid and uninsured individuals in their communities.

#### **Proposed Calculation of the Upper Payment Limit**

The current regulations allow states some flexibility to calculate the UPL. The proposed regulation would eliminate this flexibility and require states to calculate the UPL using one of two prescribed methodologies: 1) Medicare cost-to-charge ratio based on allowable Medicare costs, or 2) Medicare payment-to-charge ratio based on allowable charges. CMS would require states to use the Medicare cost report to calculate these ratios. The resulting applicable ratio would then be multiplied by the Medicaid charges identified on Medicaid claims to determine the UPL.

This new requirement is completely contrary to CMS's statement that this is a minor rule that "clarifies" current policy. This is a major change that would have a significant impact on the hospital outpatient UPL calculation. In addition, by requiring that the Medicare cost report be used to calculate the UPL and by prescribing the cost report schedules that would be used to generate these calculations, CMS is eliminating costs for services, such as physician services and GME, that states currently may include in the outpatient UPL calculation.

GNHYHA is also concerned that the proposed methodology makes no allowances for "flat rate" hospitals that do not have detailed departmental charges. Because these hospitals do not report departmental charges on Worksheets C and D of the Medicare cost report, the methodologies prescribed by CMS in the proposed rule would be inherently inappropriate. The alternate proposed methodology of applying a payment-to-charge ratio using Worksheet E would be similarly inappropriate. The Medicare program allows such hospitals to use an alternate methodology to apportion costs based on utilization statistics rather than charges on its Medicare

cost report, and a similar policy exception is needed to calculate the UPL for such hospitals. While we firmly oppose CMS's proposed methodologies for calculating the outpatient UPL, if CMS were to finalize its proposal, the Agency must allow states to use an alternative methodology to calculate the UPL for flat rate hospitals.

Finally, GNYHA believes that there is a technical error in the description of how states should treat deductibles, coinsurance, and bad debt amounts in the calculation of Medicare payments for the UPL using a payment-to-charge ratio. In the proposed rule, CMS states, "Additionally, States must ensure that bad debts are not over-reported by including deductibles and coinsurance and reimbursable bad debt in Medicare payments. If deductible and coinsurance are added onto the Medicare payments, the State should remove reimbursable bad debts included in the Medicare payment." The proper computation of Medicare payments would be to include deductibles and coinsurance, to subtract bad debt cost, and to add bad debt reimbursement.

#### **UPL Calculation for Clinic Services**

CMS also proposed to change the methodology that states use to compute the UPL for private clinic services. The proposal would require states to either adopt a reimbursement methodology that pays a certain percentage, limited to 100%, of the facility component of the Medicare Physician Fee Schedule (PFS) or to demonstrate that in the aggregate the Medicaid rates for these services are less than what Medicare would have paid. CMS would require that such a comparison be based on an analysis of the reimbursement rates at the CPT code level. The Medicare reimbursement rates under the PFS are known to be far below cost and woefully inadequate.

This proposed policy is contrary to CMS's longstanding policy of approving a cost-based reimbursement methodology for private clinic services under the Medicaid program and would have significant implications for access to clinic services for Medicaid beneficiaries. Such clinics primarily serve Medicaid and uninsured individuals and such drastic cuts in funding would severely limit their ability to continue to provide vitally needed services to the underserved in their communities. CMS should modify its proposal to allow a cost-based UPL for private clinics.

#### **Fiscal and Regulatory Impact**

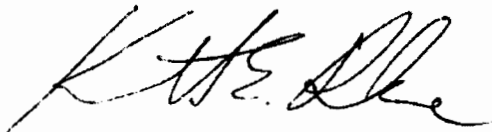
GNYHA strongly disagrees with CMS's statement that the fiscal impact of this rule would be minimal. This is a major rule that proposes broad and sweeping changes to the Medicaid program that will have a significant impact on individual state Medicaid programs, coverage of hospital outpatient services, and impose significant cuts to hospital revenues. In describing the minimal impact of the proposed rule, CMS fails to recognize the administrative costs that states would incur in order to demonstrate compliance with the proposed UPL calculation, which include, but are not limited to, changes in State Plans and regulatory and statutory changes at the state level with respect to reimbursement systems and benefits structures of the Medicaid program. The impact of these proposed changes on hospital revenues from the loss of DSH funding and coverage of certain costs, including GME, is similarly not acknowledged.

**Recommendation: GNYHA strongly urges CMS to rescind the proposed rule and to suspend any further regulatory actions that affect the issues and provisions subject to the moratorium in P.L. 110-28.**

If you have any questions regarding our comments, please contact Elisabeth Wynn, Assistant Vice President, Finance, at (212) 259-0719.

My best.

Sincerely,

A handwritten signature in black ink, appearing to read "K. E. Raske". The signature is fluid and cursive, with a large initial "K" and a long, sweeping underline.

Kenneth E. Raske  
President

**Submitter :** Dr. William Lawrence, Jr.  
**Organization :** North Carolina Division of Medical Assistance  
**Category :** State Government

**Date:** 10/29/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

North Carolina submits the attached comments.

CMS-2213-P-54-Attach-1.PDF



North Carolina Department of Health and Human Services  
Division of Medical Assistance

2501 Mail Service Center • Raleigh, N. C. 27699-2501  
Tel 919-855-4100 • Fax 919-733-6608

Michael F. Easley, Governor  
Dempsey Benton, Secretary

William W. Lawrence, Jr., M.D., Acting Director

October 29, 2007

Mr. Kerry N. Weems  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
P.O. Box 8016  
Baltimore, MD 21244-8016


RE: CMS – 2213-P - Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit (Vol. 72, No. 188), September 28, 2007

Dear Mr. Weems:

The North Carolina Division of Medical Assistance welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding changes to Medicaid policy as it relates to federal clarification of outpatient clinic and hospital facility services definition and the upper payment limit of those services. North Carolina strongly opposes this CMS proposed rulemaking change to Medicaid policy.

As stated in the September 28, 2007, Federal Register, page 55161, CMS recognizes that Medicaid covers more services than Medicare; however, it is CMS' opinion that an "economic and efficient UPL should include only services to which there exists a Medicare equivalent". By taking this position, CMS is denying reimbursement of Medicaid costs for a significant segment of North Carolina's Medicaid population, children, pregnant women, and young adults. At a minimum, the UPL for outpatient services should be the Medicaid cost as allowed by the CMS Provider Reimbursement Manual 15 and calculated using the CMS 2552 cost reporting methodology.

The Division of Medical Assistance appreciates the opportunity to comment and express its concerns regarding the proposed rules. If CMS has any questions or needs clarification, DMA personnel will be pleased to respond.

Sincerely,  
  
William W. Lawrence, Jr., MD





**Cc: Dempsey Benton  
Dan Stewart  
T. H. Galligan  
Roger Barnes  
North Carolina Hospital Association  
National Association of State Medicaid Directors**

**Submitter :** Mr. Stan Rosenstein  
**Organization :** California Department of Health Care Services  
**Category :** State Government

**Date:** 10/29/2007

**Issue Areas/Comments**

**Clinic Upper Payment Limit**

Clinic Upper Payment Limit

see attachments

**GENERAL**

GENERAL

see attachments

**Medicaid Outpatient Hospital  
Service and Rural Health Care  
Services**

Medicaid Outpatient Hospital Service and Rural Health Care Services

see attachments

**Outpatient Hospital Service and  
Rural Health Clinic Services**

Outpatient Hospital Service and Rural Health Clinic Services

see attachments

**Outpatient Hospital and Clinic  
Seravices: Application of Upper  
Payment Limits**

Outpatient Hospital and Clinic Seravices: Application of Upper Payment Limits

see attachments

**Upper Payment Limits**

Upper Payment Limits

see attachments

CMS-2213-P-55-Attach-1.PDF

CMS-2213-P-55-Attach-2.PDF

CMS-2213-P-55-Attach-3.PDF

CMS-2213-P-55-Attach-4.PDF

CMS-2213-P-55-Attach-5.PDF

CMS-2213-P-55-Attach-6.PDF

#55



State of California—Health and Human Services Agency  
Department of Health Care Services



SANDRA SHEWRY  
Director

ARNOLD SCHWARZENEGGER  
Governor

October 29, 2007

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-2213-P, Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Dear Sir or Madam:

The Department of Health Care Services (DHCS), on behalf of the State of California, appreciates this opportunity to comment on the proposed regulation changes. Please find California's comments below in response to the Notice of Proposed Rule Making (NPRM) (CMS-2213-P) published at 72 Fed. Reg. 188 (September 28, 2007). The NPRM proposes amendments to 42 C.F.R. Parts 440 and 447.

The Centers for Medicare & Medicaid Services' (CMS') proposed regulations would amend the definition and scope of outpatient hospital services and the corresponding upper payment limited (UPL) for outpatient hospital and clinic services. CMS's proposed rule also would prohibit the use of all-inclusive rates.

The State of California objects to these proposed regulations based on their potential negative impact on public and private hospitals that provide safety net services for Medicaid beneficiaries and others, which could place this critical care in jeopardy. CMS's proposed rule would have the effect of limiting outpatient hospital services and reducing payments for clinic services by changing UPL calculations.

**COMMENTS:**

**1. A 60-day comment period should have been allowed.**

CMS concluded that its proposed rule does not impose new information collection and reporting requirements and, therefore, it did not have to comply with the mandatory 60-day comment period. However, allowing only a 30-day comment period for this proposed rulemaking is clearly insufficient given the potential impact of the proposed changes.

The proposed rule threatens to affect California's Medi-Cal program in major ways. At a minimum, the proposed rule will create substantial new administrative burdens. The revisions to the UPL alone create significant new information

collection requirements requiring hospital and clinic cost reports and Medi-Cal fee schedules.

Further, any change to the definition of outpatient hospital services will clearly affect each and every state, not just the one unnamed state mentioned by CMS. Further, any change to the manner in which the UPL is calculated for hospital outpatient services and clinics also will apply to each and every state. Therefore, limiting the comment period to 30 days is insufficient and does not comply with various federal laws and regulations, including the Paperwork Reduction Act.

**2. The proposed rule may violate a legislative moratorium**

The proposed rule may violate a legislative moratorium on CMS action. On January 18, 2007, CMS published its proposed regulation on Cost Limits for Providers Operated by Units of Government, 72 Fed. Reg. 2236. On May 25, 2007, as part of the US Troop Readiness, Veterans Care, Katrina Recovery, and Iraq Appropriations Act of 2007, Congress prohibited the Secretary of Health and Human Services from taking "any action" to "finalize or otherwise implement" the regulation proposed on January 18, 2007. Pub. L. No. 110-28, § 7002 (2007). Four days after that instruction, the final rule was published in the Federal Register, with a purported effective date of July 30, 2007.

Although CMS has stated its intent to comply with the moratorium provision, it is apparent that the current proposal will significantly affect reimbursement to hospitals and clinics of all types, including those operated by units of government. CMS-2258-FC, which is subject to a moratorium, purports, among other things, to "clarify] the documentation required to support a Medicaid certified public expenditure" and to "limit[] Medicaid reimbursement for health care providers that are operated by units of government to an amount that does not exceed the health care provider's cost of providing services to Medicaid individuals." 72 Fed. Reg. 29748 (May 29, 2007). The proposed rule would alter the definition of outpatient hospital services, thereby altering the costs and expenditures that CMS would deem acceptable under CMS-2258-FC. Thus, CMS's claim that the proposed rule concerns matters different from those addressed in CMS-2258-FC is incorrect.

**3. The proposed regulation would reduce costs that can be claimed from the Safety Net Care Pool and from the Disproportionate Share Hospital program.**

The proposed amendments to the definition of outpatient hospital services would affect payments to the designated public hospitals that currently claim federal funds for the cost of services provided to the uninsured from the Safety Net Care

Pool (SNCP) established under California's section 1115 *Medi-Cal Hospital/Uninsured Care Demonstration* (Demonstration).

If the regulations are promulgated, CMS likely would apply the proposed new requirements to California's Special Terms and Conditions (STCs), which states that a new federal law or regulation must be applied to the Demonstration. If the proposed rule is applied to the STCs and the definition of outpatient hospital services is narrowed, then the costs of providing outpatient hospital services that are currently claimed from the SNCP likely would be reduced. This would put unknown amount of available SNCP funding (\$586 million in federal funds) at risk.

Additionally, the proposed rule could result in a reduction of the costs claimed by California's hospitals under the Disproportionate Share Hospital (DSH) program. In 2005, California began using certified public expenditures to claim DSH funding up to 100 percent of costs. Again, any change in the definition of outpatient hospital services that narrows the services, and corresponding costs of those services, likely would result in reduced payments to hospitals under the DSH program. This also could result in California's hospitals being unable to claim the full DSH annual allotment of \$1.023 billion.

**4. The Health Care Coverage Initiative under California's Demonstration could be affected.**

\$180 million in federal funds from the SNCP were made available for three years (2007-2010) to reimburse public expenditures made under the Health Care Coverage Initiative, which expands health care coverage for low-income, uninsured individuals in California. The counties (governmental entities) that operate the Coverage Initiative (CI) programs, claim federal funds through their certified public expenditures. Any change in the definition of outpatient hospital services that narrows the services, and the corresponding costs of the services, could result in reduced payments to CI counties.

**5. The proposal would prohibit the use of all-inclusive rates.**

The proposed rule would prohibit the long-accepted practice of paying all-inclusive rates for outpatient hospital services. By excluding professional services from the definition of outpatient hospital services, the new rule would require California to pay physicians and other professionals separately from the facility, requiring amendments to California's state plan.

The proposed rule does not point to any statutory reason or public policy that would support its position. Both professional services and outpatient hospital

services are mandatory services under Section 1905(a) of the Act and nothing in the Act requires that they be separately reimbursed.

**6. Using the Medicare definition of outpatient hospital services for Medicaid is inappropriate.**

The Medicare definition of outpatient hospital services is targeted to the elderly and disabled who are enrolled in that program. By contrast, Medicaid targets younger and more vulnerable patients who face barriers to access to care and are therefore more likely than Medicare patients to use a hospital in their community as their "medical home." The Medicare definition of outpatient hospital services is too narrow and does not appear to include services that have traditionally been covered as outpatient hospital services for the Medicaid population, including, among other, dental and vision services and some types of preventive care.

**7. The UPL calculation for outpatient hospital services improperly excludes graduate medical education (GME) costs, in violation of the congressional moratorium.**

On May 25, 2007, as part of the US Troop Readiness, Veterans Care, Katrina Recovery, and Iraq Appropriations Act of 2007, Congress prohibited the Secretary of Health and Human Services from taking "any action" to "finalize or otherwise implement" any regulation prohibiting Medicaid reimbursement for GME costs. The cost-to-charge and payment-to-charge ratios in the proposed rule are defined to exclude GME costs. Accordingly the proposed UPL is in violation of the congressional moratorium.

**8. The UPL calculation for clinic services is extremely burdensome and complex and its application may result in Medicaid rates that cannot ensure access to services.**

Rather than using cost as a proxy for the UPL as is currently allowed, the proposed rule would require California to calculate a UPL for private clinics (non Federally Qualified Health Centers (FQHCs)) by finding a methodology that (1) ensures clinics are not paid greater than 100% of the Medicare rate (provide a reasonable estimate) or, (2) shows that an aggregate of the Medicaid fee schedule rate are less than what Medicare would pay (based on the CMS Common Procedure Coding System (CPT) codes), for equivalent services. This would require a comparison on a procedure-by-procedure basis to the amount Medicare pays for equivalent services. This would entail taking information from

thousands of lines on Medicare's detailed fee schedules and making additional complex adjustments to these numbers to remove components that CMS contends are not reimbursable as clinic services under Medicaid.

This proposed UPL calculation is extremely burdensome and complex and could result in rates of payment that do not ensure access to services.

**9. California's Health Care Reform Initiative could be seriously impacted.**

Under California's Health Care Reform (HCR) Initiative, outpatient hospital services will be paid at 100 percent of the federal UPL. Any change in the definition of outpatient hospital services that narrows the services and results in a reduction of the UPL will have a negative affect on the amount of reimbursement California's hospitals may receive for these services.

For the reasons discussed above, California urges CMS to withdraw the proposed rule. Should CMS insist upon proceeding with the proposed rule, we urge CMS to reissue the proposed rule with at least a 60-day comment period, and to substantially modify its proposal in accordance with the foregoing comments.

If you have any questions, or if we can provide further information, please contact me at (916) 440-7400.

Sincerely,

A handwritten signature in black ink, appearing to read "Stan Rosenstein", with a long horizontal flourish extending to the right.

Stan Rosenstein  
Chief Deputy Director  
Health Care Programs

cc: See next page

The Centers for Medicare & Medicaid Services  
Page 6  
October 29, 2007

cc: Mr. Toby Douglas  
Deputy Director  
Health Care Policy  
Department of Health Care Services  
1501 Capitol Avenue, MS 4000  
Sacramento, CA 95899-7413

Mr. Keith Berger  
Executive Director  
California Medical  
Assistance Commission  
770 L Street, Suite 1000  
Sacramento, CA 95814

Mr. Joe Munso  
Deputy Secretary  
Office of Program and Fiscal Affairs  
California Health and  
Human Services Agency  
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Mr. Bob Sands  
Assistant Secretary  
Office of Program and Fiscal Affairs  
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Ms. Nancy Hutchison, Chief  
Safety Net Financing Division  
Department of Health Care Services  
1501 Capitol Avenue, MS 4504  
P.O. Box 997413  
Sacramento, CA 95899-7413



**Submitter :** Mr. John Bluford  
**Organization :** Truman Medical Centers  
**Category :** Hospital

**Date:** 10/29/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

I am writing on behalf of Truman Medical Centers (TMC) in opposition to the proposed rule referenced above. This rule jeopardizes an estimated \$10 million or more annually in Medicare/Medicaid funding for our hospital. The Proposed Rule violates a recent legislative moratorium on implementation of a cost limit on payments to governmental providers or restrictions on Medicaid graduate medical education (GME) payments.

TMC is Western Missouri's tier 1 Trauma Center and is staffed to accept critically ill and injured patients 24 hours a day. Currently three in four patients are Medicaid-eligible or uninsured. Last year TMC provided about \$80 million in uncompensated services at cost and over \$145 million in Medicaid services. Furthermore, TMC treats Kansas City, Missouri's most vulnerable population including the elderly and low-income families as well as individuals with chronic health challenges such as Diabetes, Asthma, HIV/AIDS, Sickle Cell and severe mental illnesses. Additionally, TMC delivers almost half of the babies born yearly in Kansas City, Missouri and operates one of the area's busiest Neonatal Intensive Care Units.

If promulgated, these proposed rules would threaten TMC's ability to continue providing necessary outpatient medical services to the community. Because of the increasing uncompensated care burden, TMC is under extreme financial stress. Over the last two years, TMC has accumulated a loss of \$20 million dollars and is currently unable to make needed capital purchases. Further reductions in funding would seriously curtail TMC's ability to provide many of the community-based primary and preventive Ambulatory Care services to our most at-risk population.

Because we feel the proposed rule violates the Moratorium, we urge CMS to withdraw it.

TMC also has major concerns regarding the proposed rule's financial impact as well as the impact on community health services:

" Impact on Medicaid DSH

While this is not acknowledged by CMS, the proposed rule will significantly reduce our Medicaid Disproportionate Share Reimbursement by eliminating many of the uncompensated outpatient services from a hospital's DSH cap.

" Outpatient Interns and Resident Costs

The proposed rule would reduce outpatient reimbursement for interns and resident costs which are a direct violation of the Moratorium, and would also result in a loss of dollars needed to educate and train the community's future doctors and other health care professionals.

" Definition of Outpatient Services

CMS's decision to eliminate reimbursement for Medicaid services covered in the State Plan is not consistent with the Medicaid statute. It ignores significant differences in the scope and purpose of the Medicare and Medicaid programs.

" Encourages Reductions in Key Ambulatory Care Services

Besides eliminating DSH reimbursement, the new rule eliminates hospital overhead from many hospital ambulatory services. This discourages safety net facilities from providing many of the community-based primary and preventive ambulatory care services that are extremely effective tools in improving community health and reducing future health care costs.

Based on the devastating impact this proposed rule would have on TMC and the health of the Kansas City, Missouri community we urge CMS to withdraw this regulation.

If you have any questions about this matter, please contact Gerard Grimaldi at (816) 404-3505.

CMS-2213-P-56-Attach-1.PDF



Office of the President

October 29, 2007

Mr. Kerry N. Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue SW  
Washington, D.C. 20201

**RE: CMS-2213-P- Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit**

Dear Mr. Weems:

I am writing on behalf of Truman Medical Centers (TMC) in opposition to the proposed rule referenced above. This rule jeopardizes an estimated \$10 million or more annually in Medicare/Medicaid funding for our hospital. The Proposed Rule violates a recent legislative moratorium on implementation of a cost limit on payments to governmental providers or restrictions on Medicaid graduate medical education (GME) payments.

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Because we feel the proposed rule violates the Moratorium, we urge CMS to withdraw it.

October 29, 2007  
Mr. Kerry N. Weems  
Page 2

TMC also has major concerns regarding the proposed rule's financial impact as well as the impact on community health services:

- **Impact on Medicaid DSH**

While this is not acknowledged by CMS, the proposed rule will significantly reduce our Medicaid Disproportionate Share Reimbursement by eliminating many of the uncompensated outpatient services from a hospital's DSH cap.

- **Outpatient Interns and Resident Costs**

The proposed rule would reduce outpatient reimbursement for interns and resident costs which are a direct violation of the Moratorium, and would also result in a loss of dollars needed to educate and train the community's future doctors and other health care professionals.

- **Definition of Outpatient Services**

CMS's decision to eliminate reimbursement for Medicaid services covered in the State Plan is not consistent with the Medicaid statute. It ignores significant differences in the scope and purpose of the Medicare and Medicaid programs.

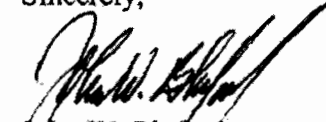
- **Encourages Reductions in Key Ambulatory Care Services**

Besides eliminating DSH reimbursement, the new rule eliminates hospital overhead from many hospital ambulatory services. This discourages safety net facilities from providing many of the community-based primary and preventive ambulatory care services that are extremely effective tools in improving community health and reducing future health care costs.

Based on the devastating impact this proposed rule would have on TMC and the health of the Kansas City, Missouri community we urge CMS to withdraw this regulation.

If you have any questions about this matter, please contact Gerard Grimaldi at (816) 404-3505.

Sincerely,



John W. Bluford  
President/CEO

JWB/gg/sh

**Submitter :** Mr. James Kirkpatrick  
**Organization :** Massachusetts Hospital Association  
**Category :** Health Care Provider/Association

**Date:** 10/29/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see attachment. Thank you.

CMS-2213-P-57-Attach-1.DOC

**MASSACHUSETTS HOSPITAL ASSOCIATION**

October 29, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***Re: (CMS-2213-P) Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit (Vol. 72, No. 188), September 28, 2007***

Dear Mr. Weems:

On behalf of member hospitals, health systems and the low-income Medicaid patients they serve, the Massachusetts Hospital Association (MHA) offers these comments with respect to the proposed rule that changes policy for federal reimbursement of Medicaid hospital outpatient services.

While the Centers for Medicare and Medicaid Services (CMS) describe the proposed rule as clarifications to current rules, MHA believes the proposed policies will have a substantial negative impact on state Medicaid programs including Massachusetts. Financial support to hospitals for care provided to low-income residents will likely be reduced and patient access issues to primary and preventative care may result due to these proposed policy changes. We believe it is unwise to implement this rule and so we strongly object. We also believe it violates a Congressional moratorium that prohibits changes to certain rules related to Medicaid payments.

Current Medicaid regulations appropriately define allowable outpatient hospital services as “preventative diagnostic, therapeutic, rehabilitative, or palliative service that (1) are furnished to outpatients; (2) are furnished by or under the direction of a physician or dentist;...” Under the proposed rule, the types of services that would no longer meet the new definition include Medicaid’s early and periodic screening and diagnostic treatment dental services for children; physician emergency department services; physical, occupational and speech therapy; outpatient clinical diagnostic laboratory services; ambulance services; durable medical equipment; and outpatient audiology services.

To no longer recognize these services as hospital services would be the antithesis of reality.

Hospitals for years have provided many of these services to varying degrees and will continue to for the foreseeable future. While CMS states that these services would be paid for to other providers in the Medicaid program, the agency fails to demonstrate that there is access to such services within the community outside of the hospital outpatient department. This concerns us greatly for the sake of Massachusetts low-income patients. We also find it troubling that CMS has decided to put forth a rule that discourages hospitals from providing primary and preventive ambulatory care which helps to reduce health care costs in the long-term.

This rule would also cause hospitals to incur additional administrative costs in identifying charges, revenues, and expenses of the services in question. Many of these services are not currently categorized into their own cost centers. To attempt to separate these items would involve manual identification, reporting inconsistencies, and accounting system changes. We do not believe it is wise to add administrative complexity to an already complex health care system which will add unnecessary costs that are best used to for medical care.

Beyond our objections to the detailed proposed changes, MHA believes that CMS' actions violate the Congressional moratorium barring the agency from regulating on matters pertaining to how states finance their Medicaid programs and fund graduate medical education (GME) payments. As you are well aware, Congress adopted this "moratorium" when it passed Public Law No. 110-28, "*U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007*" on May 24, 2007. President Bush signed this law on May 25, 2007. Section 7002 (a) of that law prohibits CMS from implementing the proposed rule "(CMS-2258 ) Medicaid Program; Cost Limit for Providers Operated by Units of Government and Provisions To Ensure the Integrity of Federal-State Financial Partnership" or any provision contained in that rule. It also prohibits CMS from restricting Medicaid payments for graduate medical education (GME).

In our view, the proposed rule in question today violates this moratorium. The proposed rule would change the hospital outpatient upper payment limit (UPL) methodology through new definitions. These definitions are part of the rule that is subject to the moratorium mentioned above. The definition of these categories is important because each category has a different aggregate UPL calculation and if changed, will likely change reimbursement for these services. Therefore, we believe CMS is in violation of the moratorium since these proposed policy changes would affect the rule which Congress directed CMS not to alter.

The rule would also violate the moratorium with regard to the treatment of GME costs because it does not allow state Medicaid programs to count GME costs in determining the Medicaid UPL. The Massachusetts Medicaid program - MassHealth - supports medical education through a small payment related to inpatient acute hospital services. This proposed rule would be in violation of the moratorium barring any regulatory activity on restricting GME or such payments made.

The proposed rule would undoubtedly put added financial pressure on an already fragile health care system in Massachusetts. As you know, our state is attempting a ground-breaking initiative to cover our state's uninsured, many of them who are low-income residents who cannot afford insurance. We rely on support from the federal government for this medical care and insurance

coverage for low-income individuals. To radically alter the way costs and payments are calculated and approved will make it all the more difficult for our state to successfully implement and sustain this landmark initiative. Hospital financials are especially uncertain at this time given the funding shifts from uncompensated care to new health insurance coverage and changes to Medicaid payments. We need the federal government to support this effort in Massachusetts, not create new administrative hurdles and definitions that are designed to reduce financial support and simply do not comport with the reality of our health care system.

**MHA strongly urges CMS to withdraw this proposed rule and suspend any further regulatory activity that affects the issues encompassed under the Moratorium.** While CMS states in the preamble that the fiscal impact of this rule would be minimal because the rule is a “clarification” of existing policy and would not result in the elimination of coverage, we find the exact opposite. We would argue that these policy changes not only will have a significant fiscal impact on our state’s Medicaid program, but could also potentially affect coverage for outpatient hospital services. These proposed policy changes could result in cuts to our state Medicaid program, cuts in payments to hospitals, and reduced access to needed services for low-income patients served by the Medicaid program.

If you have any questions regarding these comments, please feel free to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "James T. Kirkpatrick". The signature is written in a cursive style with a large, stylized initial "J".

James T. Kirkpatrick  
Vice President, Health Care Finance and Managed Care

**Submitter :** Mr. Patrick Wardell  
**Organization :** Hurley Medical Center  
**Category :** Hospital

**Date:** 10/29/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment.

CMS-2213-P-58-Attach-1.DOC



October 29, 2007

Mr. Kerry N. Weems, Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, SW  
Washington, D.C. 20201

**Ref: CMS-2213-P — Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit**

Dear Mr. Weems:

I am writing on behalf of Hurley Medical Center to express our serious concern regarding the issuance of the above-referenced Proposed Rule.<sup>1</sup> This Rule (1) unnecessarily narrows the definition of outpatient hospital services, with a significant but unacknowledged impact on disproportionate share hospital (DSH) payments; and (2) is overly prescriptive in dictating upper payment limit (UPL) methodologies for private outpatient hospitals and clinics. Of more concern, however, the Proposed Rule violates a recent legislative moratorium<sup>2</sup> (the Moratorium) on implementation of a cost limit on payments to governmental providers or restrictions on Medicaid graduate medical education (GME) payments. For these reasons, Hurley Medical Center urges CMS to withdraw the Proposed Rule immediately.<sup>3</sup>

**WHO WE ARE – An Overview of Hurley Medical Center:**

It is important to put into context, the impact that implementation of this Proposed Rule would have on Hurley Medical Center by explaining Hurley's role in the local Genesee County community, as well as the significant role we play throughout the entire state of Michigan as the region's safety net provider. While 57.5% of our patients come from Flint, 29.1% of the patients we serve live outside the City of Flint, but within Genesee County, and 13.4% of our patients come from various other regions throughout the state.

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<sup>1</sup> 72 Fed. Reg. 55158 (Sep. 28, 2007).

<sup>2</sup> U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007, Pub. L. No. 110-28, Section 7002(a).

<sup>3</sup> Hurley does not concede through submission of these comments that CMS has the authority to propose these provisions, nor to request, receive or review related comments, during the period of the moratorium.

Hurley is the largest hospital in Genesee County with 461 beds and is this region's premier public medical center and teaching hospital, providing safe, reliable, high-quality care for thousands of Genesee County residents each year. Additionally, Hurley is one of the largest employers in Genesee County and provides more than 2,200 jobs to local residents. Nine (9) unions represent Hurley's employees. As you can see, based on these facts, the financial status of Hurley has a direct impact on the economic status of our entire community. It is therefore important that you understand the total economic impact this proposed Rule will have on the Flint and Genesee County community, as well as on our patients throughout the state. This loss will negatively impact the vital services we are able to offer all our patients, particularly in the area of specialized services.

Hurley Medical Center is the only medical center in the region that provides specialty care in: Trauma, emergency and critical care services, advanced burn center, kidney transplantation, neonatal intensive care, pediatric intensive care, high risk pregnancy care, and psychiatric services. The volume of patients seeking care and treatment at Hurley is tremendous. In 2006, Hurley served 24,495 inpatients. The number of outpatient visits totaled 472,208. The number of babies born at Hurley was 2,824 and more than 78,084 patients visited Hurley's Emergency Department. We treat, on the average, at least 1450 patients a week in our Emergency Room Department. Almost 20 percent of Genesee County residents rely on Medicaid. One in five children in Genesee County lives in poverty. 27 percent of the people of Flint live in poverty, significantly more than the national average of 11.7 percent. The Flint and Genesee County community, particularly the poor, has depended on Hurley Medical Center for the past 100 years. This dependence is slowly spreading throughout the state, as our patient base grows each year.

As the region's safety net provider, it is Hurley's mission to provide care to everyone, without regard to ability pay. As the primary Medicaid health care provider in the region, Hurley provides more than \$20 million a year in uncompensated care to the community. We are still analyzing the potential negative dollar amount impact this Proposed Rule would have on Hurley, however, we can say at this point that any reduced revenue as a result of this Proposed Rule will adversely impact Hurley's ability to continue to provide medical services critical to the communities we serve and will put those services in serious jeopardy. We also serve a critical role in our community of ensuring access to ambulatory care for uninsured and Medicaid patients. The vast majority of the 472,208 outpatient ambulatory care visits is reimbursed as outpatient hospital services.

Additionally, we rely on rely upon Medicaid disproportionate share hospital (DSH) and other supplemental payments, including supplemental outpatient payments, for survival.

Our key points of objection are the following:

- CMS has violated the congressional Moratorium and, in any event, failed to clarify how this Proposed Rule interacts with the Moratorium.
- The Proposed Rule will have a potentially significant impact on DSH payments, which CMS does not acknowledge.

- The Proposed Rule discourages hospitals from expanding important ambulatory care services.
- The Proposed Rule ignores significant differences in the scope and purposes of the Medicaid and Medicare programs in requiring coterminous coverage of outpatient hospital services, and in any event requires clarification.
- CMS' definition of outpatient hospital services to exclude services otherwise covered by the State Plan is not required by the Medicaid statute and is inconsistent with language in the preamble to the Proposed Rule.
- The overly prescriptive proposed outpatient UPL excludes the costs of interns and residents, potentially resulting in millions of dollars in losses for providers in certain states, reduces state flexibility, and does not capture all Medicare-covered costs.
- The proposed private clinic UPL prohibits cost-based reimbursement without justification and includes a circular definition of the UPL for otherwise excluded dental services.

We concur in the comments detailed by the National Association of Public Hospital (NAPH) in terms of the policy and technical concerns with the above referenced aspects of the Proposed Rule.

Because the Proposed Rule violates the Moratorium, we believe that CMS is legally obligated to withdraw it, and we vehemently urge you to do so immediately. Congress enacted the Moratorium specifically to prevent CMS from taking “any action” to develop new policies in areas in which this Proposed Rule purports to regulate. Moreover, the Proposed Rule is bad policy, and would have a significant negative financial impact on both governmental and private hospitals serving Medicaid and uninsured patients. Coming in the wake of several other regulations issued by CMS that would impose large cuts on these hospitals—including the rule imposing a governmental provider cost limit and restricting sources of non-federal share funding,<sup>4</sup> the rule to eliminate Medicaid funding for graduate medical education,<sup>5</sup> and the proposed rule which has never been finalized adopting narrow new DSH policies<sup>6</sup>—CMS' latest administrative action would be devastating to public, teaching and other safety net hospitals. Cumulatively these rules would eviscerate the health care safety net as well as jeopardize care for all Americans in communities across the country.

We join the NAPH in urging you to consider the cumulative effect of the ever more restrictive Medicaid policies on the nation's safety net and the patients who rely on it for care. In addition to covering care for eligible populations, Medicaid supports an institutional safety net of health care providers that are critical to the well-being of their communities. If enacted, these rules would mean that such providers will no longer be able to train the next generation of doctors and health care professionals, to serve as the

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<sup>4</sup> 72 Fed. Reg. 29748 (May 29, 2007).

<sup>5</sup> 72 Fed. Reg. 28930 (May 23, 2007).

<sup>6</sup> 70 Fed. Reg. 50262 (Aug. 26, 2005).

health care backbone of local emergency response systems, to provide critical yet under-reimbursed specialized services such as trauma care, burn care, neonatal intensive care and emergency psychiatric care, or to provide access where none would otherwise exist for the nation's poor, uninsured and underinsured individuals. Absent a more thorough analysis of real world implications of proposed policies and their impact on the health care system, we are relying on Congress to stop these policies in their tracks.

Accordingly, we urge you to withdraw this regulation and all of the above mentioned pending regulations immediately. We urge you to adopt policies that strengthen, rather than dismantle, essential components of our nation's health care infrastructure and offer to work with you in developing such policies.

Thank you for your anticipated reconsideration of this vital issue.

Respectfully,

Patrick R. Wardell  
President & Chief Executive Officer

**Submitter :**

**Date: 10/29/2007**

**Organization :**

**Category : Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see attachment. Thank you.

CMS-2213-P-59-Attach-1.DOC



**MASSACHUSETTS HOSPITAL ASSOCIATION**

October 29, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***Re: (CMS-2213-P) Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit (Vol. 72, No. 188), September 28, 2007***

Dear Mr. Weems:

On behalf of member hospitals, health systems and the low-income Medicaid patients they serve, the Massachusetts Hospital Association (MHA) offers these comments with respect to the proposed rule that changes policy for federal reimbursement of Medicaid hospital outpatient services.

While the Centers for Medicare and Medicaid Services (CMS) describe the proposed rule as clarifications to current rules, MHA believes the proposed policies will have a substantial negative impact on state Medicaid programs including Massachusetts. Financial support to hospitals for care provided to low-income residents will likely be reduced and patient access issues to primary and preventative care may result due to these proposed policy changes. We believe it is unwise to implement this rule and so we strongly object. We also believe it violates a Congressional moratorium that prohibits changes to certain rules related to Medicaid payments.

Current Medicaid regulations appropriately define allowable outpatient hospital services as “preventative diagnostic, therapeutic, rehabilitative, or palliative service that (1) are furnished to outpatients; (2) are furnished by or under the direction of a physician or dentist;...” Under the proposed rule, the types of services that would no longer meet the new definition include Medicaid’s early and periodic screening and diagnostic treatment dental services for children; physician emergency department services; physical, occupational and speech therapy; outpatient clinical diagnostic laboratory services; ambulance services; durable medical equipment; and outpatient audiology services.

To no longer recognize these services as hospital services would be the antithesis of reality.

Hospitals for years have provided many of these services to varying degrees and will continue to for the foreseeable future. While CMS states that these services would be paid for to other providers in the Medicaid program, the agency fails to demonstrate that there is access to such services within the community outside of the hospital outpatient department. This concerns us greatly for the sake of Massachusetts low-income patients. We also find it troubling that CMS has decided to put forth a rule that discourages hospitals from providing primary and preventive ambulatory care which helps to reduce health care costs in the long-term.

This rule would also cause hospitals to incur additional administrative costs in identifying charges, revenues, and expenses of the services in question. Many of these services are not currently categorized into their own cost centers. To attempt to separate these items would involve manual identification, reporting inconsistencies, and accounting system changes. We do not believe it is wise to add administrative complexity to an already complex health care system which will add unnecessary costs that are best used to for medical care.

Beyond our objections to the detailed proposed changes, MHA believes that CMS' actions violate the Congressional moratorium barring the agency from regulating on matters pertaining to how states finance their Medicaid programs and fund graduate medical education (GME) payments. As you are well aware, Congress adopted this "moratorium" when it passed Public Law No. 110-28, "*U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007*" on May 24, 2007. President Bush signed this law on May 25, 2007. Section 7002 (a) of that law prohibits CMS from implementing the proposed rule "(CMS-2258 ) Medicaid Program; Cost Limit for Providers Operated by Units of Government and Provisions To Ensure the Integrity of Federal-State Financial Partnership" or any provision contained in that rule. It also prohibits CMS from restricting Medicaid payments for graduate medical education (GME).

In our view, the proposed rule in question today violates this moratorium. The proposed rule would change the hospital outpatient upper payment limit (UPL) methodology through new definitions. These definitions are part of the rule that is subject to the moratorium mentioned above. The definition of these categories is important because each category has a different aggregate UPL calculation and if changed, will likely change reimbursement for these services. Therefore, we believe CMS is in violation of the moratorium since these proposed policy changes would affect the rule which Congress directed CMS not to alter.

The rule would also violate the moratorium with regard to the treatment of GME costs because it does not allow state Medicaid programs to count GME costs in determining the Medicaid UPL. The Massachusetts Medicaid program - MassHealth - supports medical education through a small payment related to inpatient acute hospital services. This proposed rule would be in violation of the moratorium barring any regulatory activity on restricting GME or such payments made.

The proposed rule would undoubtedly put added financial pressure on an already fragile health care system in Massachusetts. As you know, our state is attempting a ground-breaking initiative to cover our state's uninsured, many of them who are low-income residents who cannot afford insurance. We rely on support from the federal government for this medical care and insurance

coverage for low-income individuals. To radically alter the way costs and payments are calculated and approved will make it all the more difficult for our state to successfully implement and sustain this landmark initiative. Hospital financials are especially uncertain at this time given the funding shifts from uncompensated care to new health insurance coverage and changes to Medicaid payments. We need the federal government to support this effort in Massachusetts, not create new administrative hurdles and definitions that are designed to reduce financial support and simply do not comport with the reality of our health care system.

**MHA strongly urges CMS to withdraw this proposed rule and suspend any further regulatory activity that affects the issues encompassed under the Moratorium.** While CMS states in the preamble that the fiscal impact of this rule would be minimal because the rule is a “clarification” of existing policy and would not result in the elimination of coverage, we find the exact opposite. We would argue that these policy changes not only will have a significant fiscal impact on our state’s Medicaid program, but could also potentially affect coverage for outpatient hospital services. These proposed policy changes could result in cuts to our state Medicaid program, cuts in payments to hospitals, and reduced access to needed services for low-income patients served by the Medicaid program.

If you have any questions regarding these comments, please feel free to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "James T. Kirkpatrick". The signature is written in a cursive style with a large, sweeping initial "J".

James T. Kirkpatrick  
Vice President, Health Care Finance and Managed Care



**Submitter :** Ms. Cheryl Cohen  
**Organization :** NJ Chapter of HFMA  
**Category :** Health Plan or Association

**Date:** 10/29/2007

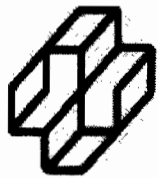
**Issue Areas/Comments**

GENERAL

GENERAL

See Attachment

CMS-2213-P-60-Attach-1.PDF



**hfma** new jersey chapter  
healthcare financial management association

October 29, 2007

Mr. Kerry Weems  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

**Re: (CMS-2213-P) Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit (Vol. 72, No. 188), September 28, 2007**

Dear Mr. Weems:

On behalf of our 1,000 member organization, the New Jersey Chapter of the Healthcare Financial Management Association (HFMA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule changing Medicaid policy for federal reimbursement of Medicaid hospital outpatient services.

CMS describes the Medicaid hospital outpatient proposed policy changes as clarifications to current rules. CMS further states that because these changes will not result in a significant financial impact, the proposed rule is not considered a major rule and, therefore, a 30-day comment period is sufficient. HFMA disagrees on all points.

The proposed rule is making major policy changes to the Medicaid program; a 30-day comment period is an insufficient time period for public comment; and CMS is violating Congress' moratorium barring the agency from regulating on matters pertaining to how states finance their Medicaid programs and fund graduate medical education (GME) payments. HFMA urges CMS to withdraw this rule and submits these comments with strong opposition to the changes proposed.

**MORATORIUM**

CMS violates the year-long moratorium secured by P.L. 110-28 because the policy changes proposed are based on provisions within the May 28 final rule that Congress explicitly instructed the agency not to implement. ((CMS-2258) *Final Rule - Medicaid Program; Cost Limit for Providers Operated by Units of Government* (Vol. 72, No. 102), May 29, 2007) CMS' proposed rule violates the moratorium in two ways.

First, the agency proposes changes to the hospital outpatient upper payment limit (UPL) methodology. The proposed changes are based on a new definition of the categories of providers (state, non-state governmental and private) found in the final rule subject to the moratorium. The definition of these categories is important because each category has a different aggregate UPL calculation. Current regulations define the three categories as: state government-owned or -operated facilities; non-state government-owned or -operated facilities; and private-owned and -operated facilities. (42 C.F.R. Section 447.321 (a)) The May 28 final rule redefines the categories by removing ownership status and the

proposed rule relies on this new definition and restates it as, “State government-operated facilities ...Non-state government-operated facilities ...privately operated facilities” (pp 55158, 55165-66).

Second, the rule violates the moratorium with regard to the treatment of GME costs. The proposed rule does not permit state Medicaid programs to count GME costs in determining the UPL – a clear violation of the moratorium barring any regulatory activity on restricting GME or such payments made.

#### **SCOPE OF HOSPITAL OUTPATIENT SERVICES AND UPL CALCULATIONS**

The proposed rule substantially departs from long-standing Medicaid policy regarding the definition of Medicaid outpatient hospital services and how costs for such services are treated for the purposes of calculating the hospital outpatient UPL. CMS bases its dramatic shift in policy on the need to align Medicaid outpatient policies with Medicare outpatient policies, although these programs serve very different populations. Medicaid serves a largely pediatric population while Medicare serves an elderly population. Yet despite these differences, CMS is proposing to narrowly define Medicaid hospital outpatient services to align it with Medicare. The only justification for aligning the hospital outpatient policies for these two programs would be to limit Medicaid federal spending for hospital outpatient programs and state Medicaid programs overall.

**Scope of Services.** Current Medicaid regulations broadly define allowable hospital outpatient services to include preventative, diagnostic, therapeutic, rehabilitative or palliative services provided under the direction of a physician or dentist in a hospital. Under the proposed rule, the types of services that are at risk for not being reimbursed through hospital outpatient programs include Medicaid’s early and periodic screening and diagnostic treatment dental services for children; physician emergency department services; physical, occupational and speech therapy; outpatient clinical diagnostic laboratory services; ambulance services; durable medical equipment; and outpatient audiology services. However, CMS does not identify a problem with current state Medicaid programs to justify this policy change. In fact, the agency states in the proposed rule’s preamble that in examining 32 state plan amendments over the last four years, CMS found only one state that defines non-hospital services as part of the outpatient hospital Medicaid set of services. (72 Fed. Reg. at 55161) In addition, while CMS states that the services no longer reimbursed through hospital outpatient departments will be paid for through other parts of the Medicaid program, the agency fails to demonstrate that there is access to such services within the community outside of the hospital outpatient department.

Further, CMS’ attempt to narrow the definition of allowable hospital outpatient services poses serious implications for Medicaid disproportionate share hospital (DSH) payments. A hospital’s uncompensated care costs help determine a hospital’s DSH reimbursement. Currently, CMS views only the costs for providing inpatient and outpatient hospital services as allowable for determining a hospital’s uncompensated care costs. The agency’s proposed narrow definition would exclude many costs now included in hospitals’ Medicaid DSH calculations, potentially limiting DSH payments to already financially strapped hospitals.

**UPL Calculations.** CMS states that the proposed changes in the UPL methodology will apply only to private outpatient hospital UPLs. While this may appear straightforward, it is not. The definition of a governmental hospital remains unresolved because it falls within the scope of the final rule that is subject to the congressional moratorium. Therefore, we find it nearly impossible to assess the change in UPL methodology because the universe is unknown.

In proposing a new methodology to determine UPL calculations, CMS violates its own description of the proposed rule as one of “clarifications.” States currently have some measure of flexibility in calculating the UPL. However, the proposed rule would limit states to two permissible methods of calculating the new UPL: Medicare cost-to-charge ratio based on Medicare allowable costs; and Medicare payments-to-

charge ratio based on allowable costs. The cost information is to be derived from hospitals' filed Medicare cost reports. The selected ratios would be multiplied by Medicaid outpatient charges based on Medicaid paid claims.

This new formula for calculating UPL would have a major impact on hospitals. For example, children's hospitals would not have their costs appropriately accounted for in the new UPL methodology, particularly the Medicare payment-to-charges ratio, because they have little to no Medicare volume. GME costs also would not be accounted for in the new UPL methodology using the Medicare cost-to-charge ratio. In addition, state Medicaid programs would face a new administrative burden in attempting to adapt their current UPL calculations to this new proposed methodology.

#### CONCLUSION

CMS states in the preamble that the fiscal impact of this rule would be minimal because the rule is a clarification of existing policy and would not result in the elimination of coverage. HFMA believes that the agency has failed to perform the due diligence necessary to make these statements. Furthermore, we would contend that these policy changes not only will have a significant fiscal impact on many state Medicaid programs, but could potentially affect coverage for outpatient hospital services.

**HFMA urges CMS to withdraw this rule and suspend any further regulatory activity that affects the issues encompassed under the moratorium secured by P.L. 110-28.** These proposed policy changes will result in cuts to state Medicaid programs, cuts in payments to hospitals, and reduced access to needed services for potentially millions of vulnerable people served by the Medicaid program.

If you have any questions, please feel free to contact me at (609) 259-3363 or [ccohen-pantheon@comcast.net](mailto:ccohen-pantheon@comcast.net).

Respectfully submitted,

*Cheryl H. Cohen*

Cheryl H. Cohen, MBA, FHFMA  
President, New Jersey Chapter of  
the Healthcare Financial Management Association

**Submitter :** Mr. Stephen Harwell  
**Organization :** Healthcare Association of New York State  
**Category :** Health Care Provider/Association

**Date:** 10/29/2007

**Issue Areas/Comments**

GENERAL

GENERAL

See attachment

CMS-2213-P-61-Attach-1.DOC



Healthcare Association  
of New York State

October 29, 2007

Kerry M. Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-2213-P  
P.O. Box 8016  
Baltimore, Maryland 21244-8016

**Re: CMS-2213-P, Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit; Proposed Rule**

Dear Mr. Weems:

The Healthcare Association of New York State (HANYS), on behalf of our more than 550 hospitals, nursing homes, home health agencies, and other health care providers, welcomes the opportunity to comment on the proposed rule related to federal reimbursement of outpatient hospital services.

HANYS objects to the issuance of this proposed rule which violates the provisions of the Congressional moratorium contained in P.L. 110-28. The moratorium prohibits the Centers for Medicare and Medicaid Services (CMS) from issuing regulations or taking administrative actions to restrict payments for graduate medical education (GME) under the Medicaid program. The current proposal would require that GME be excluded from the outpatient hospital upper payment limit (UPL) calculation, thereby restricting the ability of states to pay for GME. In addition, The Congressional moratorium prohibits CMS from implementing a May 28, 2007 rule regarding cost limits for government providers. The proposed rule uses revised definitions of provider categories for the UPL calculation that are based on regulation changes included in the May 28 final rule covered by the moratorium.

The proposed rule would revise the definition of outpatient hospital services for the Medicaid program. According to CMS, the proposal is intended to align the Medicaid definition more closely to the Medicare definition in order to improve the functionality of the upper payment limits calculation, to provide more transparency in determining available coverage in any State, and to clarify the scope of services for which Federal financial participation (FFP) is available under the outpatient hospital services benefit category. CMS presents the rule as a clarification of the definition of outpatient services that would have minimal impact and states that "the rule would not reach the economic threshold and thus is not considered a major rule." HANYS disagrees with this assessment.

HANYS believes the proposed alignment of Medicaid outpatient services to Medicare outpatient and clinic definitions would result in significant administrative burdens and financial impacts for both hospitals and states. Services provided to the Medicaid population vary greatly from the Medicare population and Medicaid programs may elect to provide many services that Medicare does not cover. The New York Medicaid program provides many services that do not fit into Medicare definitions including

Mr. Weems  
October 29, 2007

Page Two

pediatric screening programs, prenatal care, dental services, and rehabilitative services. The proposed regulation changes are so vague and broad there is little assurance all these services will be protected.

Even if access to services is protected, states would be forced to make major changes to reimbursement systems. New York State has many all-inclusive reimbursement methodologies under its Medicaid program and this proposed rule would require significant modifications to the State's Medicaid Plan. Alignment with Medicare definitions would require unbundling of some services and implementation of new payment systems. In addition, many states are developing innovative mechanisms for providing and paying for appropriate patient care. These include programs for chronic care services, disease management, and other services that may involve coordinated care across provider types. The CMS proposal would force states to structure services to match Medicare definitions and would severely inhibit such innovation.

Finally, CMS has failed to provide justification for the substantial changes that this proposal would require. CMS states that after reviewing 32 state plan amendments over the last four years, they found only one state that defined non-hospital services as part of the outpatient hospital Medicaid set of services. This record does not justify the significant administrative burdens and potential financial impacts of this proposal. Instead, CMS should continue to address such issues through the current state plan review process.

CMS has failed to perform a sufficient review of the impact of this policy change. The proposed limits on state Medicaid programs could reduce access, and threaten the health and wellbeing of millions of our most vulnerable patients. Therefore, HANYS urges CMS to withdraw this rule and suspend any additional regulatory activity that violates the moratorium mandated by P.L. 110-28.

If you have any questions regarding our comments, please contact me at [sharwell@hanys.org](mailto:sharwell@hanys.org) or at (518) 431-7777.

Sincerely,

Stephen Harwell  
Vice President  
Economics, Finance and Information

**Submitter :** Dr. Mitchell Katz

**Date:** 10/29/2007

**Organization :** San Francisco Dept. of Public Health/SFGH

**Category :** Local Government

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-2213-P-62-Attach-1.DOC





Gavin Newsom  
Mayor

Mitchell H. Katz, MD  
Director of Health

October 29, 2007

Mr. Kerry Weems, Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-2213-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

Re: Comments on Proposed Rule CMS-2213-P  
Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility  
Services Definition and Upper Payment Limit

Dear Mr. Weems:

On behalf of the San Francisco Department of Public Health and San Francisco General Hospital (SFGH), I am writing to express our opposition to CMS's Proposed Rule, CMS 2213-P, which limits the definition of outpatient hospital services and has a negative impact on DSH payments and the upper payment limit for Medicaid payments to public providers. We therefore urge CMS to withdraw this proposed rule.

California's public hospitals, including San Francisco General Medical Center are a cornerstone of the State's health care system. SFGH provides the only Level 1 trauma center in San Francisco, and serves more than 1.3 million San Francisco and northern San Mateo County residents. Annually, we serve more than 100,000 people, and care for more than 3,000 people per day. More than one-quarter of SFGH outpatient visits are covered by Medi-Cal, and 35 percent are uninsured. SFGH sees more Medi-Cal and uninsured patients than any other hospital in San Francisco. Fully 80 percent of our outpatient population either receives publicly-funded health insurance (Medi-Cal, Medicare) or is uninsured.

The proposed outpatient rule is yet another attempt by CMS to curtail Medicaid payments to public hospitals, which provide a significant amount of Medicaid services to eligible low-income and disabled patients. If this rule goes into effect, it will likely result in the reduction of critical outpatient clinic and hospital facility services that public hospitals such as SFGH are uniquely qualified to provide. For example, SFGH has the only Psychiatric Emergency Service in San Francisco, and is the largest acute and rehabilitative hospital for psychiatric patients. Furthermore, a soon-to-be-released audit by the Lewin Group finds that SFGH is near the top of benchmark hospitals in overall clinical quality and delivers cost efficient patient care.

We believe that this rule should be withdrawn for a number of reasons. First, it violates the moratorium that prevents CMS from implementing its restrictive cost-limit and GME rules. Beyond its violation of the moratorium, the rule has numerous harmful implications for Medicaid payments. Though the rule neglects to refer specifically to its negative impact on DSH payments, we are concerned that the uncompensated care costs associated with the disallowed services may no longer be included in our hospital's DSH cap. The DSH program recognizes the unique role that safety net hospitals play in the treatment of the Medicaid and uninsured patients, and any reduction to those payments will restrict our ability to continue to provide these services.

The proposed rule also changes the methodology by which the upper payment limit ("UPL") is calculated for private hospitals. The UPL currently in place bases Medicaid payments on a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles. The rule would base the UPL calculation on costs and payments for outpatient services from the Medicare cost report. As Medicare pays separately for GME costs related to outpatient services of GME, those costs are not reflected on the cost report worksheets specified in the proposed methodology, and the proposed methodology would result in the exclusion of GME costs from the DSH payments. We are concerned that CMS may attempt to apply this flawed methodology to governmentally operated hospitals.

Finally, there are a number of issues raised in the comment letter submitted by the California Association of Public Hospitals (CAPH), an organization of which we are a member, which we incorporate in these comments by reference. As discussed in the CAPH letter, the rule is not a "clarification" of existing law as CMS states, but instead involves substantive policy changes. Furthermore, the rule fails to provide an adequate Regulatory Impact Analysis, as required by Executive Order 12886. In light of CMS's failure to describe the action proposed in the rule accurately and to provide an adequate Regulatory Impact Statement, the rulemaking notice is inadequate and the rule should be withdrawn.

SFGH opposes this Medicaid rule and strongly urges CMS to withdraw it. If the rule goes into effect, we will suffer harmful effects that will affect our ability to care for our patients and communities. CMS must recognize the damage that this rule will have to our community's health care system and withdraw this proposed rule.

Sincerely,

Mitchell H. Katz, M.D.  
Director of Health

Cc: Mayor Gavin Newsom  
Eve O'Toole, MARC Associates



**Gavin Newsom**  
**Mayor**

**Mitchell H. Katz, MD**  
**Director of Health**

October 29, 2007

Mr. Kerry Weems, Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-2213-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

Re: Comments on Proposed Rule CMS-2213-P  
Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility  
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Mitchell H. Katz, M.D.  
Director of Health

Cc: Mayor Gavin Newsom  
Eve O'Toole, MARC Associates

**Submitter :** Mr. John Siracusa

**Date:** 10/29/2007

**Organization :** BIO

**Category :** Drug Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-2213-P-63-Attach-1.PDF



October 29, 2007

**BY ELECTRONIC DELIVERY**

Kerry Weems, Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

**Re: CMS-2213-P (Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit)**

Dear Acting Administrator Weems:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule clarifying the definition of outpatient clinic and hospital facility services for the Medicaid program (the "Proposed Rule").<sup>1</sup> BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

In the Proposed Rule, CMS explains that the current definition of "outpatient hospital services" under Medicaid is broader than the definition used under Medicare and is inconsistent with the applicable upper payment limit (UPL).<sup>2</sup> The UPL for Medicaid outpatient hospitals services requires the aggregate state Medicaid payments for outpatient hospital and/or clinic payments not to exceed a reasonable estimate of the amount that would be paid under Medicare payment principles.<sup>3</sup> Because services may be included in the Medicaid

<sup>1</sup> 72 Fed. Reg. 55158 (September 28, 2007).  
<sup>2</sup> *Id.* at 55159.  
<sup>3</sup> *Id.*



definition of “outpatient hospital services” that are not reimbursed by Medicare, the UPL may not reflect a comparison of similar services. To remedy this problem, CMS proposes to align the Medicaid definition with Medicare’s definition of “outpatient hospital services.” CMS states that the proposed revision would “provide greater consistency between the two federally funded programs.”<sup>4</sup> It also would help to ensure that the UPL includes only those services for which an equivalent service is reimbursed by Medicare.

BIO members produce therapies that are reimbursed by Medicaid, Medicare, and other government programs, such as the federal 340B Drug Pricing Program. Using consistent definitions across these programs helps to simplify a very complex array of regulations and pricing policies. We support CMS’s efforts to use uniform definitions and we ask CMS to implement the revised definition of “outpatient hospital services” in the final rule. We also support the proposed revisions to the definition of the UPL because they provide greater clarity to states and consistency across programs.

BIO appreciates the opportunity to offer these comments. Please feel free to contact me at 202-312-9281 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

John Siracusa  
Manager, Medicare Reimbursement  
& Economic Policy

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<sup>4</sup> Id. at 55161.

**Submitter :** Miss. Theresa Gonzales  
**Organization :** Arizona Health Care Cost Containment System  
**Category :** State Government

**Date:** 10/29/2007

**Issue Areas/Comments**

**Clinic Upper Payment Limit**

Clinic Upper Payment Limit

See Attachment

**GENERAL**

GENERAL

See Attachment

**Medicaid Outpatient Hospital  
Service and Rural Health Care  
Services**

Medicaid Outpatient Hospital Service and Rural Health Care Services

See Attachment

**Outpatient Hospital Service and  
Rural Health Clinic Services**

Outpatient Hospital Service and Rural Health Clinic Services

See Attachment

**Outpatient Hospital and Clinic  
Seravices: Application of Upper  
Payment Limits**

Outpatient Hospital and Clinic Seravices: Application of Upper Payment Limits

See Attachment

**Upper Payment Limits**

Upper Payment Limits

See Attachment

CMS-2213-P-64-Attach-1.PDF



Janet Napolitano, Governor  
Anthony D. Rodgers, Director



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Phone: 602-417-4000  
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October 29, 2007

Mr. Kerry Weems  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
**Attention CMS-2213-P**  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Dear Mr. Weems:

As Director of the Arizona Health Care Cost Containment System (AHCCCS), I am pleased to submit comments on the proposed regulations regarding the clarification of outpatient clinic and hospital facility services and the upper payment limit (UPL), published at 72 Federal Register 55158 (September 28, 2007). AHCCCS is the state agency that administers Arizona's Medicaid program, which covers over one million members.

As written, the proposed rule could have an impact on Medicaid reimbursement for outpatient hospital services and would more narrowly define outpatient hospital services, restricting mandatory approaches to calculating UPL for outpatient and clinic services. As a result, hospitals could receive lower payments since some services would no longer be reimbursable as outpatient hospital services, nor would they be included in the calculation for outpatient hospital UPL or disproportionate hospital payments (DSH). Additionally, CMS proposes to reduce states' flexibility in calculating the UPL applicable to private clinic services, requiring the use of Medicare fee schedules as the limit rather than actual costs.

**Definition of "Outpatient hospital services"**

CMS proposes to clarify what is described as "current vague regulatory language" for outpatient hospital services. CMS has concerns that the current broad definition overlaps with other covered services, resulting in higher reimbursement for identical services than would otherwise be available under the State Plan.

The proposed rule would limit the scope of services by excluding: 1) any service not treated as outpatient hospital services under Medicare; 2) services not provided by the hospital facility; and 3) services covered elsewhere in the State Plan- examples provided include are school-based services, adult day health and rehabilitative services, and services paid for under a fee schedule.

Although states would be allowed to continue covering services excluded from the proposed narrow definition of outpatient hospital services, they would not be permitted to reimburse them as outpatient hospital services. Additionally, under current CMS policy, services excluded from the narrowed definition of outpatient hospital services would no longer be eligible for DSH reimbursement because they would not be considered costs incurred by a hospital.

### **Definition of "Outpatient Hospital"**

Under the proposed rule, services can only be included in the outpatient hospital UPL if they meet the proposed definition of "outpatient hospital services" and appear on the outpatient-specific cost report worksheets. The Medicare standard for outpatient hospital services is more specific, particularly with regards to the settings that would qualify. The Medicare criteria for "provider-based status" is a complicated standard. As a result, some hospitals that are claiming a facility fee would only be eligible to receive payments for the professional services, not the facility charges.

Additionally, the proposed rule requires that in order to qualify as outpatient services, the service must be "furnished by an outpatient hospital facility, *including* an entity that *meets the standards for provider-based status* as a department of an outpatient hospital set forth in §413.65 of this chapter." 72 Fed. Reg. 55165. As a point of clarification, the phrase "including" suggests there might be other types of outpatient hospital facilities that qualify for these services other than those with the provider-based status. The preamble only discusses hospitals, facilities on hospital campus, and facilities with provider-based status. If there are other types of facilities that qualify, the rule language should clarify the facilities or refer back to the ones discussed in the preamble. Secondly, the term "meets the standards for provider-based status" suggests that the State might have the discretion to make that determination even if the hospital has not made or received a written determination from Medicare. For administrative simplification and operational ease, the rule should clearly state that the "entity has been determined by CMS to have provider-based status" so that States can refer to the CMS determination.

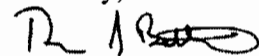
### **Definition of "Clinic Upper Payment Limits"**

The proposed rules go beyond requiring a comparison or limit to payments under "Medicare principles." Rather, they specify how the estimated Medicare payments are to be calculated, requiring a hospital by hospital calculation of the Medicaid payments using the Medicare CCRs as reported on the Medicare cost report. The rules dictate the specific section of the Medicare cost report that a state may use in calculating cost information for outpatient UPL, which may result in excluding Graduate Medical Education costs from the outpatient costs that a state can include.

For private clinics, states would be required to calculate UPL either by adopting reimbursement methodologies that pay a specified percentage, not greater than 100% for Medicare; or by demonstrating that in the aggregate, Medicaid fee schedule rates are less than what Medicare would pay based on a comparison by the CMS current Procedural Terminology Code. Under these requirements, states would not have the option of calculating the clinic UPL based on the clinic's actual costs since the Medicare outpatient fee schedule rates are much lower than costs.

Although Arizona has a waiver from the UPL requirements so long as our Fee-For-Service payments remain less than 5% of service expenditures, the rules should reiterate that UPL limitations do not apply to payments made through managed care entities. However, I urge you to reconsider the proposed changes to limiting Medicaid payments for outpatient hospital services. Thank you for this opportunity to comment on the proposed regulation.

Sincerely,



Thomas J. Betlach  
Deputy Director